



UNITED STATES PATENT AND TRADEMARK OFFICE

UNITED STATES DEPARTMENT OF COMMERCE  
United States Patent and Trademark Office  
Address: COMMISSIONER OF PATENTS AND TRADEMARKS  
Washington, D.C. 20231  
www.uspto.gov

| APPLICATION NO. | FILING DATE | FIRST NAMED INVENTOR | ATTORNEY DOCKET NO. | CONFIRMATION NO. |
|-----------------|-------------|----------------------|---------------------|------------------|
| 09/687,984      | 10/13/2000  | Shaw-Fen Sylvia Hu   | A-357B              | 1047             |

21069 7590 07/02/2002  
AMGEN INCORPORATED  
MAIL STOP 27-4-A  
ONE AMGEN CENTER DRIVE  
THOUSAND OAKS, CA 91320-1799

EXAMINER

GUCKER, STEPHEN

| ART UNIT | PAPER NUMBER |
|----------|--------------|
|----------|--------------|

1647

DATE MAILED: 07/02/2002

6

Please find below and/or attached an Office communication concerning this application or proceeding.

**Office Action Summary**

Application No.

09/687,984

Applicant(s)

HU, SHAW-FEN SYLVIA

Examiner

Stephen Gucker

Art Unit

1647

-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --  
Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 1 MONTH(S) FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If the period for reply specified above is less than thirty (30) days, a reply within the statutory minimum of thirty (30) days will be considered timely.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133).
- Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

**Status**

- 1) ☒ Responsive to communication(s) filed on 13 October 2000.
- 2a) ☐ This action is **FINAL**. 2b) ☒ This action is non-final.
- 3) ☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

**Disposition of Claims**

- 4) ☒ Claim(s) 30 and 45-50 is/are pending in the application.
- 4a) Of the above claim(s) \_\_\_\_\_ is/are withdrawn from consideration.
- 5) ☐ Claim(s) \_\_\_\_\_ is/are allowed.
- 6) ☐ Claim(s) \_\_\_\_\_ is/are rejected.
- 7) ☐ Claim(s) \_\_\_\_\_ is/are objected to.
- 8) ☒ Claim(s) 30 and 45-50 are subject to restriction and/or election requirement.

**Application Papers**

- 9) ☐ The specification is objected to by the Examiner.
- 10) ☐ The drawing(s) filed on \_\_\_\_\_ is/are: a) ☐ accepted or b) ☐ objected to by the Examiner.  
Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).
- 11) ☐ The proposed drawing correction filed on \_\_\_\_\_ is: a) ☐ approved b) ☐ disapproved by the Examiner.  
If approved, corrected drawings are required in reply to this Office action.
- 12) ☐ The oath or declaration is objected to by the Examiner.

**Priority under 35 U.S.C. §§ 119 and 120**

- 13) ☐ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).  
a) ☐ All b) ☐ Some \* c) ☐ None of:  
1. ☐ Certified copies of the priority documents have been received.  
2. ☐ Certified copies of the priority documents have been received in Application No. \_\_\_\_\_.  
3. ☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).  
\* See the attached detailed Office action for a list of the certified copies not received.
- 14) ☐ Acknowledgment is made of a claim for domestic priority under 35 U.S.C. § 119(e) (to a provisional application).  
a) ☐ The translation of the foreign language provisional application has been received.
- 15) ☐ Acknowledgment is made of a claim for domestic priority under 35 U.S.C. §§ 120 and/or 121.

**Attachment(s)**

- 1) ☐ Notice of References Cited (PTO-892) 4) ☐ Interview Summary (PTO-413) Paper No(s). \_\_\_\_\_
- 2) ☐ Notice of Draftsperson's Patent Drawing Review (PTO-948) 5) ☐ Notice of Informal Patent Application (PTO-152)
- 3) ☐ Information Disclosure Statement(s) (PTO-1449) Paper No(s) \_\_\_\_\_ 6) ☐ Other: \_\_\_\_\_

## DETAILED ACTION

### *Election/Restrictions*

1. Restriction to one of the following inventions is required under 35 U.S.C. 121:
  - I. Claims 30 and 45-50, drawn to a GDNF protein product consisting of the amino acid sequence of SEQ ID NO: 42, classified in class 512, subclass 2.
  - II. Claims 30 and 45-50, drawn to a GDNF protein product consisting of the amino acid sequence of SEQ ID NO: 44, classified in class 514, subclass 2.
  - III. Claims 30 and 45-50, drawn to a GDNF protein product consisting of the amino acid sequence of SEQ ID NO: 46, classified in class 514, subclass 2.

The inventions are distinct, each from the other because of the following reasons:

Although there are no provisions under the section for "Relationship of Inventions" in M.P.E.P. § 806.05 for inventive groups that are directed to different products, restriction is deemed to be proper because these products constitute patentably distinct inventions for the following reasons. Each of SEQ ID NOS: 42, 44, and 46 is a unique sequence, requiring a unique search of the prior art. Searching all of the sequences in a single patent application would provide an undue search burden on the examiner and the USPTO's resources because of the non-coextensive nature of these searches.

2. Because these inventions are distinct for the reasons given above and have acquired a separate status in the art as shown by their separate search requirements, restriction for examination purposes as indicated is proper.
3. This application contains claims directed to the following patentably distinct species of the claimed invention:

A method for affecting the survival or function of neurons comprising administering a pharmaceutical composition of GDNF with the amino acid sequence of X-(Cys<sup>41</sup>-Cys<sup>133</sup>)-Y wherein X is selected from the group:

Art Unit: 1647

- a. G
- b. RG
- c. NRG
- d. SEQ ID NO: 3
- e. SEQ ID NO: 4
- f. SEQ ID NO: 5
- g. SEQ ID NO: 6
- h. SEQ ID NO: 7
- i. SEQ ID NO: 8
- j. SEQ ID NO: 9
- k. SEQ ID NO: 10
- l. SEQ ID NO: 11
- m. SEQ ID NO: 12
- o. SEQ ID NO: 13
- p. SEQ ID NO: 14
- q. SEQ ID NO: 15
- r. SEQ ID NO: 16
- s. SEQ ID NO: 17
- t. SEQ ID NO: 18
- u. SEQ ID NO: 19
- v. SEQ ID NO: 20
- w. SEQ ID NO: 21

Art Unit: 1647

- x. SEQ ID NO: 22
- y. SEQ ID NO: 23
- z. SEQ ID NO: 24
- aa. SEQ ID NO: 25
- bb. SEQ ID NO: 26
- cc. SEQ ID NO: 27
- dd. SEQ ID NO: 28
- ee. SEQ ID NO: 29
- ff. SEQ ID NO: 30
- gg. SEQ ID NO: 31
- hh. SEQ ID NO: 32
- ii. SEQ ID NO: 33
- jj. SEQ ID NO: 34
- kk. SEQ ID NO: 35
- ll. SEQ ID NO: 36
- mm. SEQ ID NO: 37
- nn. SEQ ID NO: 38

Applicant is required under 35 U.S.C. 121 to elect a single disclosed species for prosecution on the merits to which the claims shall be restricted if no generic claim is finally held to be allowable. Currently, claims 46-50 are generic.

Art Unit: 1647

Applicant is advised that a reply to this requirement must include an identification of the species that is elected consonant with this requirement, and a listing of all claims readable thereon, including any claims subsequently added. An argument that a claim is allowable or that all claims are generic is considered nonresponsive unless accompanied by an election.

Upon the allowance of a generic claim, applicant will be entitled to consideration of claims to additional species which are written in dependent form or otherwise include all the limitations of an allowed generic claim as provided by 37 CFR 1.141. If claims are added after the election, applicant must indicate which are readable upon the elected species. MPEP § 809.02(a).

Should applicant traverse on the ground that the species are not patentably distinct, applicant should submit evidence or identify such evidence now of record showing the species to be obvious variants or clearly admit on the record that this is the case. In either instance, if the examiner finds one of the inventions unpatentable over the prior art, the evidence or admission may be used in a rejection under 35 U.S.C. 103(a) of the other invention.

**In order to be fully responsive, Applicant must select one from Groups I-III. Applicant is advised that I-III is not a species election requirement; rather, I-III is a restriction requirement.**

**If Applicant selects Groups I-III, one species from the “X” group must also be chosen to be considered fully responsive.**

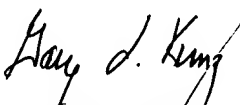
Art Unit: 1647

Any inquiry concerning this communication or earlier communications from the examiner should be directed to Stephen Gucker whose telephone number is (703) 308-6571.

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Gary Kunz can be reached on (703) 308-4623. The fax phone numbers for the organization where this application or proceeding is assigned are (703) 308-4242 for regular communications and (703) 308-4242 for After Final communications.

Any inquiry of a general nature or relating to the status of this application or proceeding should be directed to the receptionist whose telephone number is (703) 308-0196.

Bridget E. Bunner  
Art Unit 1647  
June 28, 2002

  
**GARY L. KUNZ**  
**SUPERVISORY PATENT EXAMINER**  
**TECHNOLOGY CENTER 1600**